

### REMARKS

Reconsideration and withdrawal of the rejections set forth in the Office action dated May 27, 2005 are respectfully requested.

#### I. Amendments

Claim 42 and 45 are amended to recite the peptide is specifically immunoreactive with HEV antibodies. Basis for these amendments can be found throughout the specification and in original claim 4.

Claims 47, 51, 57, and 61 are amended to recite the composition comprises a preparation for use as a vaccine in immunizing an individual against HEV. Basis for these amendments can be found on pages 65-66.

No new matter is added by way of these amendments.

#### II. 35 U.S.C. §112, first paragraph

Claims 45-61 were rejected under 35 U.S.C. §112, first paragraph as allegedly containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which is most nearly connected, to make and/or use the invention.

Claims 47, 51, 57, and 61 were rejected under 35 U.S.C. §112, first paragraph as allegedly containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which is most nearly connected, to make and/or use the invention.

Applicants respectfully traverse these rejections.

The first paragraph of 35 U.S.C. §112 requires that the specification of a patent enable any person skilled in the art to which it pertains to make and use the claimed invention without undue experimentation (e.g., *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir., 1991).

#### A. Rejection of Claims 45-61

The Examiner indicates the claims are enabling for ORF2-homologous peptides and fragments which are specifically immunoreactive with antibodies

present in individuals infected with HEV (Office action mailed May 27, 2005, page 2). The present claims, as in amended claim 42, describe a composition comprising an isolated peptide prepared by expression of a sequence shown from base number 5147 through 7129 in SEQ ID NO:6 and the sequence shown from base number 5117 through 7096 in SEQ ID NO:10. The peptide is specifically immunoreactive with HEV antibodies. As seen on page 19, the sequence from 5147 to 7129 of SEQ ID NO:6 as well as pages 23-27 for the sequence from 5117 through 7096 in SEQ ID NO:10 are both ORF-2 sequences. Thus, the presently claimed composition comprises an isolated peptide that is specifically immunoreactive with HEV antibodies and is prepared with an expression vector comprising ORF-2 sequences of SEQ ID NO:6 or SEQ ID NO:10.

B. Rejection of claims 47, 51, 57, and 61

The Examiner states the specification does not reasonably provide enablement for a vaccine. However, the Examiner indicates the specification is enabling for an immunogenic or immunoreactive composition. Claims 47, 51, 57, and 61 are all amended to recite the vaccine is for use in immunizing an individual against HEV. Guidance for the preparation and use of a peptide vaccine is described on pages 65-66. Based on the amendments and the teaching in the specification, one skilled in the art would be enabled to make and use the claimed invention as recited in claims 47, 51, 57, and 61.

In view of the amendments and the teaching in the specification, Applicants respectfully request withdrawal of the rejections under 35 U.S.C. §112, first paragraph.

III. Obviousness-Type Double Patenting

Claims 42, 44, 45, 48, 49, 52-55, and 58-59 were rejected under the judicially created doctrine of obviousness type double patenting as allegedly unpatentable over claims 5-10 and 24-29 of U.S. Patent No. 5,824,649.

Claims 45, 54, 55, 58, and 59 were rejected under the judicially created doctrine of obviousness type double patenting as allegedly unpatentable over claim 1 of U.S. Patent No. 6,214,970 or 6,291,641, or 5,770,689, or claims 1, 3, 4 of U.S. Patent No. 5,885,768.

Claims 42-61 were rejected under the judicially created doctrine of obviousness type double patenting as allegedly unpatentable over claims 1-13 of U.S. Patent No. 5,741,490.

Claims 42-61 were provisionally rejected under the judicially created doctrine of obviousness type double patenting as allegedly unpatentable over claims 1-7 of U.S. Patent Application No. 10/165,868.

Claims 42-61 were provisionally rejected under the judicially created doctrine of obviousness type double patenting as allegedly unpatentable over claims 22 and 23 of U.S. Patent Application No. 09/769,066.

A Terminal Disclaimer prepared in accordance with 37 C.F.R. §1.321(b) and (c) is enclosed. The signed Terminal Disclaimer obviates these obviousness-type double patenting rejection.

#### IV. Conclusion

Applicants respectfully submit that pending claims 42-61 are in condition for allowance. The undersigned invites the Examiner to call (650) 838-4410 with any questions or comments. The Commissioner is hereby authorized and requested to charge any deficiency in fees herein to Deposit Account No. 50-2207.

Respectfully submitted,  
Perkins Coie LLP



Jacqueline F. Mahoney  
Registration No. 48,390

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**Correspondence Address:**  
Customer No. 22918